

## REMARKS

### Status of the Claims

Claims 107, 124-142, 149-154, 157-159, 165, 166, and 170-172 are currently pending and under examination. Claims 108-124, 143-148, 155, 156, 160-164, and 167-169 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 170-172 have been added.

### Amendments to the Claims

Claims 125, 126, 128, 130, 131, 134-142, 149, 150, 154, 157, 159, 165, and 166 have been amended. New claims 170-172 have been added. The amendments to the claims and the addition of the new claims are supported by the specification as summarized below.

Representative support for the amendment to claim 125 can be found in canceled claim 156; paragraph 57, line 20, and paragraph 89, line 9.

Claims 126, 128, 130, 131, 134-142, 149, 150, 157, 159, 165, and 166 have been amended to delete dependency to canceled claim 124.

Claim 142 has also been amended to add additional polyhydric alcohols. Support for the amendment can be found in claim 124 and on page 17, lines 20 and 21.

Claim 154 has been amended to delete an inadvertent typographical error.

Support for new claim 170 can be found in claim 124 and on page 17, lines 20 and 21.

Support for new claim 171 can be found in original claim 142.

Support for new claim 172 can be found in original claim 167.

The amendments to the claims and addition of new claims do not include prohibited new matter.

### Allowable Subject Matter

The Office Action has indicated that claim 107 is allowable and that claim 156 would be allowable if rewritten in independent form including all the limitations of the base claim.

Applicants have canceled claim 156 and have incorporated the limitations of claim 156 into claim 125. Thus, in addition to claim 107, claim 125 and its dependent claims should be allowable.

Rejections Under 35 U.S.C. 103(a)

A. Claims 124, 125, 128-133, 137-142, 149, 157-159, 166, 167, and 169 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freistedt *et al.* in view of Horowitz *et al.*

Claim 124 has been canceled. Claim 125 has been amended to include the limitation that the one or more tissues are contacted with a composition comprising propylene glycol and at least one other polyhydric alcohol and a penetration enhancer prior to irradiation. Claims 128-133, 137-142, 149, 157-159, 166, 167, and 169 depend upon claim 125 and therefore include the limitations of claim 125.

Neither Freistedt *et al.* nor Horowitz *et al.* teach contacting tissues with propylene glycol, one other polyhydric alcohol, and a penetration enhancer prior to irradiation. Moreover Horowitz *et al.* do not teach sterilization of tissues. Although Freistedt *et al.* disclose irradiating soft tissues, Horowitz *et al.* only disclose sterilization of blood. Soft tissues and blood are structurally and functionally distinct products. A person having ordinary skill in the art would not reasonably expect soft tissue and blood to use the same conditions for sterilization. Accordingly, the cited references do not provide the motivation necessary to combine the references and modify the method of sterilization disclosed in the cited references to arrive at the method recited in the claims with reasonable expectation of success. Thus, the combination of the cited references does not render the claimed invention obvious.

B. Claims 126, 127, 134, 135, and 150-154 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freistedt *et al.* in view of Horowitz *et al.* as applied to claim 125 above, and further in view of Peterson.

The limitations of claim 125, as it stands, are discussed immediately above. Claims 126, 127, 134, 135, and 150-154 depend upon claim 125 and therefore include the limitations of claim 125. Claims 126 and 127 add the limitation that the tissues are hard tissues. Claim 134 adds the limitation that the tissue is maintained in an inert atmosphere, and claim 135 adds the limitation that the tissue is maintained under vacuum. Claims 150-154 add the limitation of the content of the residual solvent.

The deficiencies of Freistedt *et al.* and Horowitz *et al.* are discussed above. Moreover, Freistedt *et al.* teach sterilization of soft tissues, and Horowitz *et al.* disclose sterilization of blood. Soft tissue, blood, and hard tissue are structurally and functionally distinct products. A person having ordinary skill in the art would not reasonably expect soft tissue, blood, and hard tissue to use the same conditions for sterilization.

Peterson does not cure the deficiencies of Freistedt *et al.* and Horowitz *et al.* Although Peterson teach sterilization of biologically active compositions and disclose the additional limitations of claims 126, 127, 134, 135, and 150-154, Peterson does not teach contacting biologically active compositions with propylene glycol, at least one other polyhydric alcohol, and a penetration enhancer prior to irradiation and therefore does not teach the limitations of claim 125.

Accordingly, the cited references do not provide the motivation necessary to combine the references and modify the method of sterilization disclosed in the cited references to arrive at the method recited in the claims with reasonable expectation of success. Thus, the combination of the cited references does not render the claimed invention obvious.

C. Claim 136 is rejected under 35 U.S.C. §103(a) as being unpatentable over Freistedt *et al.* in view of Horowitz *et al.* as applied to claim 125 above, and further in view of Chanderkar *et al.*

The limitations of claim 125, as it stands, are discussed above (see Section A). Claim 136 depends upon claim 125 and therefore includes the limitations of claim 125. Claim 136 adds the limitation that the irradiation is applied at a rate of at least about 0.3 kGy/hour to at least about 30.0 kGy/hour.

The deficiencies of Freistedt *et al.* and Horowitz *et al.* are discussed above (see Section A). Chanderkar *et al.* do not cure the deficiencies of Freistedt *et al.* or Horowitz *et al.* because Although Chanderkar *et al.* teach the additional limitation of claim 136, Chanderkar *et al.* do not teach sterilization of tissues by irradiation and do not teach contacting tissues with propylene glycol, at least one other polyhydric alcohol, and a penetration enhancer prior to irradiation and therefore do not teach the limitations of claim 125. Chanderkar *et al.* only disclose sterilization of lyophilized fibrinogen in the presence of an electron scavenger. Fibrinogen is a protein that is

structurally and functionally different from a tissue. A person having ordinary skill in the art would not reasonably expect tissue and protein to use the same conditions for sterilization. Accordingly, the cited references do not provide the motivation necessary to combine the references and modify the method of sterilization disclosed in the cited references to arrive at the method recited in the claims with reasonable expectation of success. Thus, the combination of the cited references does not render the claimed invention obvious.

D. Claim 165 is rejected under 35 U.S.C. §103(a) as being unpatentable over Freistedt *et al.* in view of Horowitz *et al.* as applied to claim 125 above, and further in view of Okrongly *et al.*

The limitations of claim 125, as it stands, are discussed above (see Section A). Claim 165 depends upon claim 125 and therefore includes the limitations of claim 125. Claim 165 adds the limitation that the tissues are packaged prior to irradiation.

The deficiencies of Freistedt *et al.* and Horowitz *et al.* are discussed above (see Section A). Although Okrongly *et al.* teach the additional limitation of claim 165, Okrongly *et al.* do not cure the deficiencies of Freistedt *et al.* or Horowitz *et al.* because Okrongly *et al.* do not teach sterilization of tissues by irradiation and do not teach contacting tissues with propylene glycol, at least one other polyhydric alcohol, and a penetration enhancer prior to irradiation, which are the limitations of claim 125. Okrongly *et al.* only disclose irradiating macromolecules in the presence of trehalose. A person having ordinary skill in the art would not reasonably expect tissue and macromolecules to use the same conditions for sterilization. Accordingly, the cited references do not provide the motivation necessary to combine the references and modify the method of sterilization disclosed in the cited references to arrive at the method recited in the claims with reasonable expectation of success. Thus, the combination of the cited references does not render the claimed invention obvious.

### Conclusion


The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited.

Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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